EMA/91859/2026
EMEA/H/C/006636

Palsonify (*paltusotine*)

A plain-language overview of Palsonify and why it is authorised in the EU

What is Palsonify and what is it used for?

Palsonify is a medicine that is used in adults for the treatment of acromegaly. Acromegaly is a condition in which the body makes too much growth hormone after normal growth of the skeleton has finished. This leads to an increase in a hormone called insulin-like growth factor 1 (IGF-1) which usually causes the bones of the hands, feet, head and face to grow larger than normal.

Acromegaly is rare, and Palsonify was designated an 'orphan medicine' (a medicine used in rare diseases) on 26 February 2025. Further information on the orphan designation can be found on the EMA website.

Palsonify contains the active substance paltusotine.

How is Palsonify used?

Palsonify can only be obtained with a prescription. It is available as tablets that are taken by mouth on an empty stomach once daily. Patients receive a starting dose which is increased over several weeks based on blood levels of IGF-1 or on clinical signs and symptoms.

For more information about using Palsonify, see the package leaflet or contact your doctor or pharmacist.

How does Palsonify work?

Acromegaly is a disease in which the pituitary gland (a small gland located at the base of the brain) makes too much growth hormone.

The active substance in Palsonify, paltusotine, is a synthetic version of the hormone somatostatin (a somatostatin analogue), which helps control how much growth hormone the body makes. Paltusotine works by attaching to and activating somatostatin receptors (targets) in the body. When these receptors are activated, they reduce the signals that cause the pituitary gland to release growth hormone. This lowers levels of both growth hormone and IGF-1.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

What benefits of Palsonify have been shown in studies?

A main study showed that Palsonify was more effective than placebo (a dummy treatment) at restoring IGF-1 levels to their normal level. Normal IGF-1 level is an established measure to confirm that acromegaly is well controlled. The study involved adults with acromegaly who were not receiving treatment at the time of the study and had elevated IGF-1 levels. After 24 weeks, around 56% of those who received treatment with Palsonify (30 out of 54) had IGF-1 levels within the normal range compared with around 5% of those given placebo (3 out of 57).

A second main study showed that Palsonify was more effective than placebo at maintaining IGF-1 levels. The study involved adults with acromegaly who were already receiving treatment for their condition. After 36 weeks of treatment around 83% of those who received treatment with Palsonify (25 out of 30) had IGF-1 levels within the normal range compared with around 4% of those given placebo (1 out of 28).

Studies carried out with Palsonify are described in more detail in the medicine's assessment report.

What are the side effects and restrictions with Palsonify?

For the full list of side effects and restrictions with Palsonify, see the package leaflet.

The most common side effects with Palsonify (which may affect more than 1 in 10 people) include diarrhoea. Nausea (feeling sick) and abdominal (belly) pain or discomfort may affect up to 1 in 10 people.

Why is Palsonify authorised in the EU?

Palsonify was effective at enabling adults with acromegaly to achieve and maintain disease control. Although Palsonify is less effective in adults with high IGF-1 levels, this has been reflected in the medicine's product information so that prescribers are aware of it.

While other somatostatin analogues authorised in the EU are given as injections, Palsonify is available as a tablet which is taken by mouth. The Agency considered that this may help patients follow their treatment more consistently and avoid the discomfort of monthly injections. The safety profile of Palsonify was similar to that of other somatostatin analogues.

The European Medicines Agency therefore decided that Palsonify's benefits are greater than its risks and that it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Palsonify?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Palsonify have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Palsonify are continuously monitored. Suspected side effects reported with Palsonify are carefully evaluated and any necessary action taken to protect patients.

Other information about Palsonify

Palsonify received a marketing authorisation valid throughout the EU on 23 April 2026.

Further information on Palsonify, including the package leaflet and assessment report, can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/palsonify.

For information about the availability of this medicine in your country, contact your national competent authority.

This overview was last updated in 03-2026.